IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : **10/679,772**
Filed : October 6, 2003
Applicant : Barry M. Yomtov, et al.
Title : Medical Device for Controlled Drug Delivery and Cardiac Monitoring and/or Stimulation

TC/AU : 3762
Examiner : Alyssa M. Alter

Docket No. : 17509-0075
Customer No. : 29052

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John T. Santini Jr., hereby declare that:

1. I am the President of MicroCHIPS, Inc., which is the assignee of the above-identified patent application. I have a Ph.D. in chemical engineering from Massachusetts Institute of Technology and over 13 years of experience in the development of micro-reservoir based devices for the protection and selective exposure or release of chemicals, such as pharmaceuticals, diagnostic reagents, or enzymes on biosensors. I am an inventor on 18 issued U.S. patents directed to this technology.

2. I have reviewed the Office Action mailed June 23, 2006, in connection with the present patent application. I also have reviewed U.S. Patent Publication No. 2002/0072784 by

Sheppard Jr., et al. (hereinafter "Sheppard")[1] upon which the Examiner relies to reject claims 1-14, 16-30, and 33-34. The Examiner's rejection of the claims of the present application appears to be based upon a substantial misunderstanding of the teaching of Sheppard.

3. The claims of the present application require, in pertinent part, means for disintegrating a reservoir cap by electrothermal ablation. This is described at least at page 19, line 15 to page 20, line 1, of the specification. For instance, the structure of the device provides that "when an effective amount of an *electrical current is* *applied through the leads and reservoir cap*, the temperature of the reservoir cap is locally increased due to resistive heating, and the heat generated within the reservoir cap increases the temperature sufficiently to cause the reservoir cap to be electrothermally ablated (i.e., ruptured)." This is analogous to the failure of a conventional electrical fuse.

4. The Examiner contends that from Sheppard's disclosure at page 3, paragraph 27, of thermally responsive reservoir caps, "it follows that they would release their contents by electrothermal ablation." (Page 4, Office Action). This is simply incorrect. Sheppard does not disclose or suggest any type of reservoir cap disintegration mechanism that involves electrothermal ablation. Rather, Sheppard discloses an electro*chemical* mechanism or a thermal mechanism. In the former, an electric potential is applied between an anodic reservoir cap and a separate cathode to cause the reservoir cap to oxidize and dissolve into a surrounding conductive fluid. In the latter, electrical energy is applied to the reservoir cap to modulate its porosity (but not to disintegrate it) or to a resistor "*nearby*", *but distinct from*, the reservoir cap, to heat and

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[1] For the record, I am named as a joint inventor in Sheppard application, and MicroCHIPS Inc. is the assignee of that application as well.

rupture or disintegrate the reservoir cap. See paragraphs 27 and 59. Sheppard simply does not disclose or suggest applying an electrical current directly through a reservoir cap to cause it to heat and disintegrate. Sheppard thus teaches no mechanism or design for reservoir cap disintegration by electrothermal ablation.

5. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

9-19-06
Date

John T. Santini Jr.